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Ref: 8EPR-SR

May 8, 2001

Dr. David Campagna
ATSDR
Division of Health Studies
Health Investigations Branch
Executive Park, Building 4
1600 Clifton Road, NE, E-31
Atlanta, GA 30333

RE: Vasquez Boulevard/ Interstate 70 NPL Site, Proposed Soil Pica, Soil Ingestion and Health Outcome Investigation

Dear Dr. Campagna:

Thank you for providing EPA the opportunity to participate in the Advisory Committee for ATSDR's proposed Soil Pica, Soil Ingestion and Health Outcome Investigation at the Vasquez Boulevard/Interstate 70 (VB/I70) Site. I understand that a written plan which includes study protocols is currently under development. Some aspects of the plan have been discussed at meetings of the Advisory Committee. Based on those discussions, EPA believes that certain modifications to the proposed approach are critical to the usefulness and success of the study. Please consider the following comments as you develop the final written plan:

1. EPA believes the basic objectives of the study should be to gain information on the frequency of soil pica behavior, the mass of soil ingested when soil pica behavior is exhibited, and the health consequences associated with exposure as a result of soil pica behavior in the population of children in the VB/I70 study area.

2. We understand that ATSDR has chosen a cross sectional study design. Given this choice, we believe it is critical to define your study target population to include as many children as possible (at least 1000 children) between the ages of six months and 6 years old. The study should not be restricted to children with expected high contact or intake of soil or to those residing on high arsenic soils.

3. It is critical to the study objectives to collect the following information on all children investigated: age; home address; the arsenic level in the home yard soil (if not already measured); general behavioral traits; hair arsenic level; inorganic and total urinary arsenic level from a one time sample; outdoor play activities over 3 days prior to the urine sample; diet over 3 days prior to the urine sample; symptoms of illness over 3 days prior to urine

sample. It will not be sufficient to simply tell participants to restrict their diet. Collecting information on what was specifically eaten is critical to assessing whether exposures can be attributed to diet or other sources.

4. The study plan should include detailed information about how the data will be analyzed to ensure that no data needs are overlooked. Key items of data analysis include:

A. Use the distribution of the urinary arsenic levels to estimate the frequency of high arsenic intakes.

B. Use the distribution of the hair arsenic levels to evaluate the distribution of long term average exposures to arsenic

C. Classify high urinary inorganic arsenic results as attributable to diet or soil based on total urinary arsenic and/or dietary history

D. Assess the prevalence of clinical symptoms in children with high urinary arsenic compared to low urinary arsenic.

E. Compare the prevalence of clinical signs in children with urinary arsenic spikes attributed to soil intake to clinical signs in children with urinary arsenic spikes attributed to diet.

F. Calculate the distribution of soil intakes for urinary arsenic spikes attributed to soil intake by :

$$\text{Soil intake (g)} = \frac{\text{Concentration in urine(ug/L)* Volume urine (L)}}{\text{(Urinary excretion fraction *RBA*Conc in soil)}}$$

We look forward to receiving the study plan. If you have questions about our comments, please call me at (303) 312-6579.

Sincerely,

Bonnie Lavelle
Remedial Project Manager

cc: VB/I70 Working Group